

MODIFYING ENVIRONMENTAL RISK ASSESSMENTS: A SOFTWARE SOLUTION FOR DOCUMENT MANAGEMENT



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Environmental exposure and risk assessments are a significant component of data for the registration of chemicals, whether plant protection products, biocides or general chemicals. Reports and summaries generate large amounts of electronic documentation within standardised databases such as CADDY and IUCLID. Where additional environmental fate or effects data are added or a re-evaluation and interpretation of existing information is undertaken, this can require modifications of the documentation within the dossier which can be time consuming and costly. A way round this is the development of a software solution to automate the process, thus cutting costs. A proposed approach is discussed.

The software would follow a step-wise approach to building a product database that could be used to populate template documents with relevant values and pre-defined text. Such an approach facilitates simple adjustment of individual aspects of the product database to enable rapid updating of documents. The screenshots below illustrate aspects of the development of a product database required to produce Section Mill of a Plant Protection Product dossier (Document 1663/VI/94 Rev. 8, 22 April 1998). In this example seven steps are proposed:

Step 1: Compile background information on Product

- Physico-Chemical Properties
- Formulation
- Application Method
- GAP

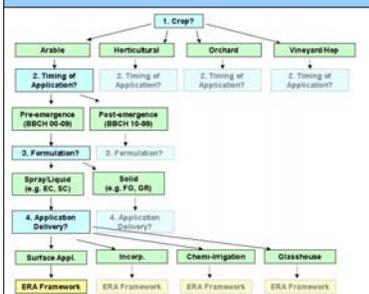
Step 2: Abstract Summary Information on Ecotoxicology

Flexible step-through process, adding tests to build databases for all relevant compartments (Aquatic, Terrestrial etc.). Selection of appropriate Assessment Factors based on data provided (where relevant – e.g. Dossiers under 98/8/EC).

Step 3: Identify the most relevant risk assessment path

Selection of appropriate risk assessment framework based on criteria defined in Step 1, taking into account (in case of a Plant Protection Product Dossier):

- Crop
- Application Timing
- Formulation
- Application method



Step 4: Identify Worst-case usage Situations

The software summarises the GAP information for the product and suggests a worst-case usage situation to be considered in the environmental risk assessment. The worst-case will vary depending upon the exposure pathways considered. This can be manually overridden.

Usage	Number of Applications	Maximum Application Interval (d)	Developmental Stage (First Application)	Maximum Application Rate (g/ha)	Directly Selected Worst Case Usage
GAP 1: Arable Wheat	3	N/A	Pre-Emergence	100	<input type="checkbox"/>
GAP 2: Vineyard	1	N/A	Pre-Emergence	175	<input type="checkbox"/>
GAP 3: Vineyard	2	14	Post-Emergence	200	<input checked="" type="checkbox"/>
GAP 4: Vineyard	2	14	Post-Emergence	90	<input type="checkbox"/>

Step 5: Calculate Exposure

For each relevant risk assessment path the software can use standard frameworks to calculate predicted exposure. Exposure calculation modules are called according to the risk assessment path identified in Step 4. In situations where modelling is required (e.g. FOCUS GW and SW) the output files can be directly interrogated and relevant information extracted for reporting.

Step 6: Calculate Risk

Calculations of Toxicity Exposure Ratios (TER), Hazard Quotients (HQ) or Risk Characterisation Ratios (RCR) can be performed according to the dossier requirements. Calculations are performed taking into account Exposure information (Step 5) and Effects data (Step 2).

Scenario	Waterbody	Max PEC (µg/L)	Reference Toxicity	TER for	TER for
13	Drift	0.475	1.27	1889	7374
14	Drift	0.326	39.57	54711	20667
15	Stream	7.749	1.08	232	8776
16	Stream	0.326	39.57	5771	20666
17	Stream	7.474	1.74	2430	9036
18	Stream	1.467	11.57	15033	56266
19	Stream	38.379	0.34	403	1772

Step 7: Present the results of the Risk Assessment

The resulting TERs, HQs or RCRs can be presented in standardised documentation formats according to dossier requirements. The software can construct the relevant sections of the documents by selecting predefined passages of text as appropriate. Where risk profiles are changed as a result of new data, existing text will be automatically modified to reflect the change. Replaced or modified text will be highlighted prior to acceptance to enable a rapid visual check of the document.

Conclusion

Based on initial investigations it is clear that there is considerable opportunity to develop bespoke software, tailored to produce and rapidly amend sections of dossiers according to standard formats. Such a tool would be extremely beneficial in reducing the costs associated with regulatory submissions.